K132258

Zimmer Dental

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Traditional 510(k)
PRE-MARKET NOTIFICATION 510(k)

510(k) SUMMARY (21CFR807.92(a))

1. Submitter's Information:

Name:	Zimmer Dental Inc.
Address:	1900 Aston Ave.
	Carlsbad, CA 92008
Phone:	760-929-4366
Contact:	Julie Lamothe

NOV 19 2013

Date Prepared: June 18, 2013

2. Device Name:

Trade Name:	Trabecular Metal Implant
Regulation Number:	872.3640
Classification Code:	DZE
Device Classification Name:	Implant, Endosseous, Root-Form

3. Predicate Device(s):

Predicate Device No. 1

Trade Name:	Trabecular ScrewVent X Implant
510(k):	K112160, K113753
Regulation Number:	872.3640
Classification Code:	DZE
Device Classification Name:	Implant, Endosseous, Root-Form

Predicate Device No. 2

Trade Name:	Screw Vent Dental Implant
510(k):	K013227, K061410
Regulation Number:	872.3640
Classification Code:	DZE
Device Classification Name:	Implant, Endosseous, Root-Form

4. Device Description:

Trabecular Metal Implant is an endosseous dental implant composed of titanium alloy and Trabecular Metal (tantalum). The implant section is designed for ease of implantation and with greater surface area for osseointegration. The implant section surface is treated to facilitate

osseointegration. In addition, the implant section is tapered with triple-lead threads.

The Trabecular Metal Implant family is currently offered in 4.1, 4.7, and 6.0mm diameters in lengths of 8, 10, 11.5, 13, and 16mm. They include two different texturing configurations: full texture to the top of the implant and texture to 0.5mm from the top of the implant. In addition, both texturing configurations of the implant have coronal grooves on the collar to within 0.64mm of the top of the implant similar to the predicate #1: *Trabecular Metal* Dental Implant. An additional *Trabecular Metal* implant with a new diameter of 3.7mmD will be offered in lengths of 10, 11.5, 13 and 16mmL. The implant-abutment interface platform diameter will be offered in a size of 3.5mm. The new device will feature MTX surface equivalent to existing Zimmer Dental implants. The MTX surface is used on the titanium body and is exposed on surfaces apical and coronal to the *Trabecular Metal*.

5. Indications for Use:

The Zimmer *Trabecular Metal* Implants are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional or delayed healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.

The 3.7mmD Zimmer *Trabecular Metal* Implants should be splinted to additional implants when used in the pre-molar region and should not be used in the molar region.

The 4.1mmD Zimmer *Trabecular Metal* Implants should be splinted to additional implants when used in the molar region.

The 4.1mmD x 8mmL Zimmer *Trabecular Metal* Implant should be splinted to additional implants when used in the pre-molar region and should not be used in the molar region.

6. Device Comparison:

The Zimmer Trabecular Metal Implant is similar to predicate device #2 Zimmer Screw Vent Implant (K013227, K061410), relative to mechanical strength and implant/abutment connection. The 3.7mmD Trabecular Metal device includes an assembly of *Trabecular Metal* (tantalum) to a titanium alloy core similar to predicate device #1, *Trabecular Metal* Implant (K112160). The threaded portion of the implant will have a tapered body with triple lead thread design, and the Trabecular Metal portion of the implant is cylindrical. The Trabecular Metal is a 3D structure similar to cancellous bone that will allow for bone

ingrowth. The new implant will be offered in a 3.7mm diameter in lengths of 10, 11.5, 13 and 16mm.

7. Technological Characteristics

Feature	**New Device** Zimmer Trabecular Metal Implant	**Predicate 1** Zimmer Trabecular Metal Implant	**Predicate 2** Screw-Vent Dental Implant
Implant Interface	Internal Hex	Internal, Hex	Internal Hex
Implant Lengths	10mm, 11.5mm, 13mm, 16mm	8.0mm, 10mm, 11.5mm, 13mm, 16mm	8.0mm, 10mm, 13mm, 16mm
Implant Diameters	3.7mm	4.1mm, 4.7mm, 6.0mm	3.3mm, 3.7mm, 4.7mm
Material	Titanium 6Al-4V Tantalum	Titanium 6Al-4V Tantalum	Titanium 6Al-4V
Collars	Machined with grooves or textured to top with grooves	Machined with grooves or textured to top with grooves	Machined
Thread Pattern	Triple lead threads, pattern tightly spaced & equal; partial cylinder type body	Triple lead threads, pattern tightly spaced & equal; partial cylinder type body	Single Lead
Surface Characteristics	MTX Surface and Trabecular Metal TM (tantalum)	MTX Surface and Trabecular Metal TM (tantalum)	MTX Surface and MP-1 HA

8. Non-Clinical Testing:

Non-clinical test data was used to support the decision of substantial equivalence. Non-clinical testing consisted of performance of fatigue and compression testing in accordance with the FDA guidance Class II Special Controls Guidance Document: Root-form Dental Implants and Endosseous Dental Implant Abutments. The testing indicates that the device is strong enough to withstand the anticipated forces and demonstrated improvements over the predicate device. Additionally, torque testing was conducted in accordance with internal Zimmer Research Protocols to indicate the strength at the apical tip of the implant is greater than the stress that the implant will see in dense cortical bone.

9. Clinical Testing:

No clinical testing was performed. Non-clinical testing was used to support the decision of substantial equivalence.

10. Conclusion:

Based on our analysis, the device is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 19, 2013

Zimmer Dental Incorporated
Dr. Julie Lamothe
Manager Regulatory Affairs
1900 Aston Avenue
CARLSBAD CA 92008

Re: K132258
Trade/Device Name: Zimmer Dental Trabecular Metal Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: October 18, 2013
Received: October 21, 2013

Dear Dr. Lamothe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for
-S FDA

Erin Keith
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132258

Device Name: ***Zimmer Dental Trabecular Metal Implant System***

Indications For Use:

The *ZimmerTrabecular Metal* Implants are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional or delayed healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.

- The 3.7mmD Zimmer Trabecular Metal Implants should be splinted to additional implants when used in the pre-molar region and should not be used in the molar region.
- The 4.1mmD Zimmer Trabecular Metal Implants should be splinted to additional implants when used in the molar region.
- The 4.1mmD x 8mmL Zimmer Trabecular Metal Implant should be splinted to additional implants when used in the pre-molar region and should not be used in the molar region.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael E. Adjodha -S
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